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STATE PROCUREMENT OFFICE
NOTICE OF AND REQUEST FOR EXEMPTION
FROM CHAPTER 103D, HRS

1. TO: Chief Procurement Officer
2. FROM: Health/State Laboratories/Medical Microbiology Branch

Department/Division/Agency

Pursuant to §103D-102(b)(4), HRS, and Chapter 3-120, HAR, the Department requests a procurement exemption to purchase the following:

3. Description of goods, services or construction:
Human Immunodeficiency Virus EIA Test Kits & Accessories

4. Name of Vendor: Abbott Laboratories

Address: 100 Abbott Park Road
Abbott Park, Illinois 60064-3500

5. Price:

\$100,000

6. Term of Contract: 12/15/09 *dkk*
From: ~~CPO Approval~~

To: 12 Months

7. Prior Exemption Ref. No.

~~09-021-C~~ *dkk*

8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State:
Procurement by competitive means is not practicable or advantageous to the State.
State Laboratories' equipment and instrument is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.

Abbott Laboratories and Bio-Rad Laboratories, at this time, manufacture the only USFDA approved products to detect HIV-1 and HIV-2 antibodies in serum available in the Nation.

Our laboratory has used the Abbott Laboratories HIV-1/2 EIA to screen serum specimens for the presence of HIV-1 and HIV-2 antibodies for over 13 years. The Abbott Laboratories' assay is a combination test (See Attached Sheet)

9. Details of the process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable:

We already use both products for different types of patient specimens so there is already fair and open competition. These are the only 2 FDA approved EIA tests for detection of HIV-1 and HIV-2 antibodies and the products serve as primary or contingency products for the SLD.

10. A description of the agency's internal controls and approval requirements for the exempted procurement:

The approval process within the Communicable Disease Division (CDD) for purchases >\$5,000 requires CDD Chief or designee approval. The STD Program Coordinator is responsible for administering/monitoring of the contract.

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8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State.

and uses a viral recombinant antigen which is believed to yield highly specific results, with a reasonable level of sensitivity. Bio-Rad Laboratories manufactures and distributes the Genetic Systems HIV-1/2 + O EIA assay, which is a combination test utilizing recombinant and synthetic peptides which produces a high level of sensitivity without a large number of false positives, while the Abbott Laboratories product is a recombinant virus mixture, which has demonstrated to be extremely specific for both HIV-1 and HIV-2 in our laboratory.

The Abbott Laboratories' product is used primarily to screen serum specimens while the Bio-Rad product will be primarily used to screen oral fluid specimens for the presence of HIV-1 and HIV-2 antibodies (See Request for Exemption from Chapter 103D, HRS, P.E. No. 09-050-B). Since the Bio-Rad product is also USFDA approved for use with serum specimens, our laboratory has already verified the product to screen serum specimens as a contingency in the event the Abbott Laboratories' product becomes unavailable to ensure continuous testing for HIV antibody.


REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS (Cont.)

12. A list of agency personnel, by position, who will be involved in the approval process and administration of the contract:		
Name	Position	Involvement in Process
Venie Lee	Acting STD Program Coordinator	<input checked="" type="checkbox"/> Approval <input checked="" type="checkbox"/> Administration
Kevin Nomura	STD/AIDS Branch PHAO	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Peter Whitar	STD/AIDS Branch Chief	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Dr. Glenn Wasserman	Communicable Disease Div. Chief	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
		<input type="checkbox"/> Approval <input type="checkbox"/> Administration
		<input type="checkbox"/> Approval <input type="checkbox"/> Administration

13. Direct inquiries to: Department: Health Contact Name: Gail Y. Kunimoto Phone Number: 453-6700 Fax Number: 453-6716
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Agency shall ensure adherence to applicable administrative and statutory requirements

14. *I certify that the information provided above is, to the best of my knowledge, true and correct.*

 Department Head	DEC 14 2009 Date
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Reserved for SPO Use Only	
15. Date Notice Posted <u>12-15-09</u>	
The Chief Procurement Officer is in the process of reviewing this request for exemption from Chapter 103D, HRS. Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, within seven calendar days or as otherwise allowed from the above posted date to: <div style="margin-left: 200px;"> Chief Procurement Officer State Procurement Office P.O. Box 119 Honolulu, Hawaii 96810-0119 </div>	
Chief Procurement Officer's comments:	

16. ☒ **APPROVED** ☐ **DISAPPROVED** ☐ **NO ACTION REQUIRED**

 2/8/2010
 Chief Procurement Officer Date